IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AVANIR PHARMACEUTICALS, INC., AVANIR HOLDING COMPANY, AND CENTER FOR NEUROLOGIC STUDY, Plaintiffs, v. PAR PHARMACEUTICAL, INC, PAR PHARMACEUTICAL COMPANIES, INC, AND IMPAX LABORATORIES, INC. Defendants.	)	C.A. No. 11-704 (LPS) (CONSOLIDATED)

PLAINTIFFS' OPENING BRIEF REGARDING
DELISTING OF THE '115 PATENT

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May 20, 2014

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I. INTRODUCTION

Defendants' delisting counterclaims are moot. The counterclaims seek a declaratory judgment requiring Plaintiffs to delete the information for U.S. Patent No. RE38,115 (the "'115 patent") from the entry for Nuedexta® in the Food and Drug Administration ("FDA") publication, "Approved Drug Products With Therapeutic Equivalence Evaluations" (the "Orange Book"). On May 16, 2014, Plaintiffs voluntarily deleted the '115 patent information from the Orange Book entry for Nuedexta®. The FDA has recorded Plaintiffs' deletion request in the Orange Book. As a result, there is no longer a justiciable controversy among the parties regarding Defendants' delisting counterclaims. Accordingly, Defendants' counterclaims should be dismissed for lack of subject matter jurisdiction.

II. BACKGROUND

This patent infringement dispute arises under the Hatch-Waxman Act. *See* 35 U.S.C. §271(e)(2)(A). The Hatch-Waxman Act states, in relevant part, that innovator drug companies ***shall*** notify the FDA of each patent that "claims the drug for which the applicant submitted the application [New Drug Application ("NDA")] or which claims a method of using such a drug and with respect to which a claim of patent infringement could ***reasonably be asserted*** if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1)(G) (emphasis added). New drug applicants complete this requirement by listing the relevant patents in the Orange Book. This is not optional, but instead, mandated by the statute.

Pursuant to 21 U.S.C. § 355(b)(1)(G), Plaintiffs listed the '115 patent in the Orange Book after receiving FDA approval for Avanir's Nuedexta® drug product. Plaintiffs had a good faith belief that Nuedexta® was covered by claims 18-21 of the '115 patent because Nuedexta® is a unit dosage formulation of 20 mg dextromethorphan and 10 mg quinidine, and was shown to be

capable of treating chronic and intractable pain in prior clinical studies. *See* D.I. 446 at 40-41; *see also* D.I. 431 at FF 5; D.I. 447 at FF 225, 228.[1] Indeed, both before and after listing the '115 patent in the Orange Book, Avanir invested great time and money into testing the use of Nuedexta® to treat chronic or intractable pain, including via a Phase 2 clinical study that was not completed until after trial in this matter had concluded. *See* D.I. 446 at 40-41; D.I. 447 at 227; D.I. 488 at 33. Because Plaintiffs had a good faith belief that the '115 patent claimed Nuedexta®, and that "a claim of patent infringement could ***reasonably be asserted*** if a person not licensed by [Plaintiffs] engaged in the manufacture, use, or sale of [Nuedexta®]," Plaintiffs were ***required*** to list the '115 patent in the Orange Book. *See* 21 U.S.C. § 355(b)(1)(G); 21 U.S.C. § 355(d)(6).

Pursuant to the Hatch-Waxman Act, when an innovator drug company brings suit against a generic drug manufacturer for infringement of Orange Book-listed patents, the generic drug manufacturer can "assert a counterclaim seeking an order requiring the holder [of the NDA] to correct or delete the patent information" listed for the drug product in the Orange Book if certain conditions are met. 21 U.S.C. § 355(j)(5)(C)(ii)(I). Here, Par and Impax asserted such counterclaims, each requesting that the Court "enter an order requiring Plaintiffs to delete the '115 patent information that they submitted to the FDA." (C.A. No. 11-705, D.I. 10 at Count III, ¶ 38; C.A. No. 11-704, D.I. 36 at Count V, ¶ 51).

On April 30, 2014, the Court issued an Opinion and Order in this action, holding, inter alia, the '115 patent valid, but not infringed. *See* D.I. 488, 489. In its Opinion and Order, the Court noted it had insufficient information to decide Defendants' delisting counterclaims, and

[1] As the Court noted, both Par and Impax conceded that their generic products met nearly all limitations of the asserted claims of the '115 patent, and challenged only the "therapeutically effective" and "without causing unacceptable side effects" limitations of those claims. *See* D.I. 488 at 12-13.

ordered supplementing briefing on this issue. *See* D.I. 488 at 38 n.11; D.I. 489 at ¶ 6. As a result of the Court's Opinion, and to avoid further burdening both the parties and this Court with this issue, on May 16, 2014, Avanir voluntarily requested that the FDA delete the patent information for the '115 patent from the Orange Book listing for Nuedexta®. (*See* Ex. A.) On May 19, 2014, the FDA entered Avanir's delisting request in the Orange Book. (*See* Ex. B.)

III. THE COURT LACKS SUBJECT MATTER JURISDICTION OVER DEFENDANTS' DELISTING COUNTERCLAIMS

Defendants' delisting counterclaims are moot. Plaintiffs have already deleted the '115 patent information from the Orange Book. Thus, there is no justiciable controversy among the parties regarding Defendants' delisting counterclaims. Accordingly, the Court should dismiss those claims for lack of subject-matter jurisdiction. *See* Fed. R. Civ. P. 12(h)(3) ("If the court determines at any time that it lacks subject-matter jurisdiction, the court must dismiss the action."); *see also Spectronics Corp. v. H.B. Fuller Co.*, 940 F.2d 631, 633-34 (Fed. Cir. 1991) ("The existence of an actual controversy is an absolute predicate for declaratory judgment jurisdiction. When there is no actual controversy, the court has no discretion to decide the case.") (citation omitted).

IV. CONCLUSION

For the reasons set forth herein, Par's and Impax's delisting counterclaims (C.A. No. 11-705, D.I. 10 at Count III; C.A. No. 11-704, D.I. 36 at Count V) should be dismissed for lack of subject matter jurisdiction.

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May 20, 2014

CERTIFICATE OF SERVICE

I hereby certify that on May 20, 2014, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on May 20, 2014, upon the following in the manner indicated:

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